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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,333	02/17/2004	Keith Leslie Williams	Q107293	9422
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SUITE 800				
WASHINGTON, DC 20037				
EXAMINER				
GORDON, BRIAN R				
ART UNIT		PAPER NUMBER		
1797				
MAIL DATE		DELIVERY MODE		
11/13/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/781,333

**Applicant(s)**

WILLIAMS ET AL.

**Examiner**

Brian R. Gordon

**Art Unit**

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10-10-08.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4, 11-19, 21, 25 and 26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 11-19, 21, 25-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 09/403,196.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 10, 2008 has been entered.

### ***Response to Arguments***

2. Applicant's arguments filed October 10, 2008 have been fully considered but they are not persuasive.

Applicant has amended the claim to positively claim an array including samples in an "arbitrary" pattern. This amendment is directed to new matter not supported by the specification or drawings. The term "arbitrary" is not mentioned in the specification. As such, it is unclear structural implication(s) intended from the inclusion of the term. The examiner's position is that the term arbitrary goes to the mental state or choice of an operator or individual that constructs or manufactures the array. The mental state or choice of an operator is not considered further limiting of an apparatus. Applicant implies that Figures 1 and 3, illustrates an "arbitrary" array 100 on membrane 102. The examiner asserts that one cannot look at the figures or image of an array and determine the mental state or intent of the creator (operator or automated device) of the array.

Therefore, as previously stated the amendment is directed to new matter not properly supported by the specification or drawings.

However, the examiner asserts that the array of Balch may be considered arbitrary for the operator can choose which wells will receive samples. Figure 5c of Balch illustrates an arbitrary array.

As to the image recorder, applicant's arguments are directed to intended use. Applicant does not assert Balch does not include an image recorder. Applicant asserts in is not necessary in Balch to determine the position of the samples in the array. It's also not necessary the one use the image recorder of applicant's system in the desired manner. One can also employ applicant's image recorder for another purpose as well. The standard for distinguishing a claimed apparatus from prior art is not based upon whether or not an element is used in the manner as intended by applicant. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. The CCD imaging system of Balch et al is capable of "recording" the position of biosites in the arrays. (see column 6, lines 31-41). Furthermore Balch et al. discloses the system may comprise a scanning mechanism (column 30, lines 43-51).

It should be further noted the amended "for" clauses of elements (a)-(c) of claim 1 are directed to the intended use and/or desired function of each of the elements.

In view of such the claims are rejected as given herein below.

***Claim Rejections - 35 USC § 112***

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3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-4, 11-19, 21, and 25-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no support for the claim as amended. See Response to Arguments.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what is meant by the term "arbitrary". The term does not add any further structural limitations to the device.

***Claim Rejections - 35 USC § 102***

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
8. Claims 1-4, 11-19, 21, and 25-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Balch et al. US 6,479,301

Balch et al. devices for preparing a reaction substrate for use as an assay device, and methods of using these devices. The devices prepare reaction substrates comprising arrays of biosites bound to reaction substrates. The devices have a plurality of bundled capillary tubes that convey capture probes from a storage area for eventual deposition onto a biosite on a reaction substrate.

Each biosite comprises a circle of approximately 25-200 microns in diameter. (column 9, lines 46-47).

The multiplexed assay can be designed in a standard 96 well microtiter plate format for room temperature operation to accommodate conventional robotic systems utilized for sample delivery and preparation. Also, the proximal CCD-based imager (image recorder) with a graphical user interface will enable the automation of the parallel acquisition of the numerous hybridization test results. The CCD imaging system software provides automated filtering, thresholding, labeling, statistical analysis and quantitative graphical display of each probe/target binding area within seconds (column 6, line 31+).

The accompanying proximal CCD detector/imager offers high spatial and digital resolution. In the preferred embodiment, CCD will support the imaging of hundreds to thousands of individual biosites on a reaction substrate. Together with 16 bit digital imaging, a highly quantitative image of the high density of biosites is achieved.

Specifically the device includes an ink-jet printer to be employed for printing the biological fluids to form the biosites, proximal CCD detector/imager, bound universal capture probes are arranged in an array of biosites attached to a solid support (for

extraction), various labels for identifying molecules, the CCD can provide simultaneous imaging and spectroscopy (analyzer) in the same image.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, 1st Fri. Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian R Gordon/  
Primary Examiner  
Art Unit 1797